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| APPLICATION NO. | FIL | ING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------|-----------------------|------------|----------------------|-------------------------|------------------|
| 09/675,323 | 09 | /28/2000 | Henry A. Lardy | HOLISED.063A 2363 | |
| 26551 | 26551 7590 06/23/2006 | | | EXAMINER | |
| | | RMACEUTICA | PESELEV, ELLI | | |
| 4435 EASTGATE MALL SUITE 400 | | | ART UNIT | PAPER NUMBER | |
| SAN DIEGO |), CA 921 | 21 | 1623 | | |
| | | | | DATE MAILED: 06/23/2006 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | | | |
|--|---|---|-----------------------------|--|--|--|--|--|
| | | 09/675,323 | LARDY ET AL. | | | | | |
| | Office Action Summary | Examiner | Art Unit | | | | | |
| | | Elli Peselev | 1623 | | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | | |
| Status | | | | | | | | |
| 1) 又 | Responsive to communication(s) filed on 11 M | av 2006. | | | | | | |
| · | This action is FINAL . 2b) ☐ This action is non-final. | | | | | | | |
| 3) | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | | |
| | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | | |
| Dispositi | on of Claims | | | | | | | |
| 4)🖂 | 4)⊠ Claim(s) <u>33-39,56-59,61,63-65 and 67-79</u> is/are pending in the application. | | | | | | | |
| | 4a) Of the above claim(s) 33-39 and 70-79 is/are withdrawn from consideration. | | | | | | | |
| 5) | 5) Claim(s) is/are allowed. | | | | | | | |
| 6)⊠ | ☑ Claim(s) <u>56-59, 61, 63-65 and 67-69</u> is/are rejected. | | | | | | | |
| 7) | Claim(s) is/are objected to. | | | | | | | |
| 8) | B) ☐ Claim(s) are subject to restriction and/or election requirement. | | | | | | | |
| Applicati | on Papers | • | | | | | | |
| 9) 🔲 🤈 | The specification is objected to by the Examine | r. | | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | | |
| Priority u | nder 35 U.S.C. § 119 | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | | | |
| | 1. Certified copies of the priority documents have been received. | | | | | | | |
| | 2. Certified copies of the priority documents have been received in Application No | | | | | | | |
| | 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | |
| A441 | 4-2 | | | | | | | |
| Attachment | | △□·· ·· - | (DTO 440) | | | | | |
| | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) | 4) L Interview Summary (Paper No(s)/Mail Da | | | | | | |
| 3) Inform | nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) No(s)/Mail Date | | atent Application (PTO-152) | | | | | |

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Claims 33-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 8, 2003.

Newly submitted claims 70-79 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The newly presented claims 70-79 are directed to pharmaceutical formulations and belong to the same invention as claims 33-39 which have been withdrawn from consideration as being directed to the nonelected invention, wherein the election was made without traverse.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 70-79 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 56-59, 61, 63-65 and 67-69 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 15 of copending Application No. 10/319,356 for the reasons set forth in the Office Action of November 18, 2005.

Applicant's arguments filed May 11, 2006 have been fully considered but they are not persuasive.

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Applicant contends that claim 15 of the copending application has been cancelled and that the claims in the copending application are directed to the treatment of inflammation conditions. This argument has not been found persuasive since no such amendment has been found in the copending application.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev

ELLI PESELEV
PRIMARY EXAMINER
GROUP 1200

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